REMARKS

Applicant wishes to express his appreciation for the courtesies extended Applicant's representatives, Joseph Mahoney and Thomas Stiebel, during the December 6, 2001 interview with the Examiner and Minna Moezie.

In the final Office Action dated November 23, 2001, claims 32-33, 35-43, 45-49, 57-73, and 75-100, were rejected; claims 1-31, and 51-56 were withdrawn from consideration; and claims 44 and 77 were objected to. Upon entry of this Amendment, claims 33, 35, 36, 41, 42, 45, 48, 49, 57-59, 62, 64, 75-83, 88-93, and 97-99, and 101-210 are pending and under consideration in the present application.

I. Support in Specification for Amended and New Claims

Applicant respectfully submits that no new matter has been added by way of this amendment:

Support for claims 33, 45, 103, 116, 150, and 163, can be found at least on page 35, lines 11-13, of the specification.

Support for claims 35, 36, 57, 110-112, and 157-159 , can be found at least on page 48, line18; and on page 52, lines 16-21, of the specification.

Support for claims 41, 42, 75-83, 101, 102, 114, 115, 123-131, 135-137, 149, 161, 162, 170-178, 182-184, and 197-199, can be found at least on page 14, lines 4-7, of the specification.

Support for claims 48, 117, and 164, can be found at least on page 18, lines 11-16, of the specification.

Support for claims 49, 118, and 165, can be found at least on page 17, line 7-10, of the specification.

Support for claims 58, 119, and 166, can be found at least on page 17m line 18-23, of the specification.

Support for claims 59, 120, and 167, can be found at least on page 22, lines 11-14, of the specification.

Support for claims 62, 121, and 168, can be found at least on page 15, lines 11-16, of the specification.

Support for claims 64, 122, and 169, can be found at least on page 19, lines 6-7, of the specification.

Support for claims 88, 90, 104, 106, 151, and 153 and can be found at least on page 47, lines 22-23, of the specification.

Support for claims 89, 90, 105, 106, 152, and 153, can be found at least on page 47, lines 23-26, of the specification.

Support for claims 91, 92, 97, 107, 113, 108, 154, 155, and 160, can be found at least on page 54, lines 7-14, of the specification.

Support for claims 93, 109, and 156, can be found at least on page 51, lines 4-6, of the specification.

Support form claims 98, 99, 132, 133, 179-180, can be found at least on page 54, lines 17-20, of the specification.

Support for claims 134, 181, and 196, can be found at least on page 11, lines 19-21, of the specification.

Support for claims 135-137, 140-141, 187-188, 182-184, 197-199, and 202-203, can be found at least on page 14, lines 4-7, of the specification.

Support for claims 139-143, 186-190, and 201-205, can be found at least on page 17, lines 18-20, of the specification.

Support for claims 138, 185, 200, can be found at least on page 51, lines 4-6, of the specification.

Support for claims 144, 191, and 206, can be found at least on page 54, lines 4-7, of the specification.

Support for claims 145-147, 192-194, and 207-209, can be found at least on page 17, lines 5-10, of the specification.

Support for claims 148, 195, and 210, can be found at least on page 51, lines 4-7, of the specification.

II. Rejections under 37 C.F.R. 1.75(c)

Claims 84-87, 94, and 100 were objected to under 37 C.F.R. 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. As recommended by the Examiner, claims 84-87, 94, and 100, have been rewritten. Reconsideration and withdrawal of this objection is respectfully requested.

III. Rejections under 35 U.S.C. § 112

Claims 35, 41-43 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The Examiner stated that the employment of a comma between sildenafil and citrate in claim 35 renders the claim indefinite as to whether citrate is intended to be a pharmaceutical encompassed thereby. Claim 35 has been amended to better define the invention. Applicant requests reconsideration and withdrawal of this rejection in view of the amended claim.

The Examiner stated that claim 41 recites the limitation "the composition" in the claim, and that there is insufficient antecedent basis for this limitation in the claim. Claim 41 has been amended to better define the invention. Applicant requests reconsideration and withdrawal of this rejection in view of the amended claim.

The Examiner stated that claim 42 recites the limitation "the enhancer" in the claim, and there is insufficient antecedent basis for this limitation in the claim. Claim 42 has been amended to better define the invention. Applicant requests reconsideration and withdrawal of this rejection in view of the amended claim.

The Examiner stated that claim 43 recites the limitation "the thickener" in the claim, and there is insufficient antecedent basis for this limitation in the claim. Claim 43 has been cancelled. Applicant requests withdrawal of this rejection in view of cancellation of this claim.

IV. Claim Objections

Claims 44 and 74 were objected to as being dependent upon rejected base claim 32. The Examiner stated that the claims would be allowable if rewritten in independent form including all the limitations of the base claim and any intervening claims. It is also acknowledged by the Applicant that the Examiner stated that the claimed method of treating male erectile dysfunction employing the specified combination of agents in claims 44 and 74 in the recited amounts is not seen to be taught or suggested by the prior art.

As recommended by the Examiner, claims 44 has been rewritten in independent form to include all of the limitations of the base claim and any intervening claims. Claim 74 has been cancelled.

Applicant requests reconsideration and withdrawal of this rejection in light of the amended, new and cancelled claims.

V. Rejections under 35 U.S.C. § 103

Claims 32-33, 35-43, 45-49, 57-73, and 75-100 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Omar (U.S. Patent No. 5,730,987) and Mak *et al.* (WO 99/24041-A1) and Moreland *et al.* (Life Sciences 1998, 62(2), 309-318) in view of Allen (WO 96/27372-A1). Of these claims, claim 32 and claim 100 were independent and have now been cancelled. Claims 33, 35-43, 45-49, 57-73, and 75-99 were dependent from claim 32. Claims 44 and 74 were objected to as being dependent upon a rejected base claim 32.

It is also acknowledged by the Applicant that the Examiner stated that the claimed method of treating male erectile dysfunction employing the specified combination of agents in claims 44 and 74 in the recited amounts is not seen to be taught or suggested by the prior art. The Examiner further stated that claims 44 and 74 would be allowable if rewritten in independent form including all the limitations of the base claim and any intervening claims.

As recommended by the Examiner, claim 44 has been rewritten in independent form to include all of the limitations of the base claim and any intervening claims. Claim 74 has been cancelled. The amounts of ingredients comprising the composition have been amended to be commensurate with the scope disclosed in the specification.

As for the remaining claims, claim 100 has been cancelled, and claims 33, 35, 36, 41, 42, 45, 48, 49, 57-59, 62, 64, 75-83, 88-93, and 97-99 have been amended to depend from new claim 101. New claims 196-210 also depend from claim 101. New independent claims 102 and 149 have all the limitations of claim 101. New claims 103-148 depend from claim 102, and new claims 150-195 depend from claim 149.

Applicant requests reconsideration and withdrawal of this rejection in light of the amended, new, and cancelled claims.

VI. Conclusion

With entry of the above Amendment and in view of the foregoing remarks, it is respectfully submitted that claims 33, 35, 36, 41, 42, 45, 48, 49, 57-59, 62, 64, 75-83, 88-93, and 97-99, and 101-210 are in condition for allowance.

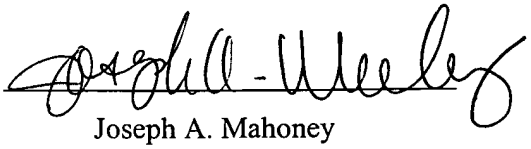
Also submitted herein, on a separate page titled "Version with Marking to Show Changes Made to the Claims," is a marked up copy of prior pending claims 33, 35, 36, 41, 42, 45, 48, 49, 57-59, 62, 64, 75-83, 88-93, and 97-99. This page shows the changes made to these prior pending claims and how these claims as amended now stand before the Patent Office.

Also submitted herein, on a separate page titled "Version with Marking to Show Changes Made to the Specification," is a marked up copy of the rewritten paragraphs and how they have been amended.

It is respectfully submitted in view of the foregoing Amendment and Remarks that all of the objections and rejection in the final Office Action dated November 23, 2001 have been overcome and should be withdrawn. Accordingly, reconsideration and withdrawal of the outstanding rejections and allowance of claims 33, 35, 36, 41, 42, 45, 48, 49, 57-59, 62, 64, 75-83, 88-93, and 97-99, and 101-210 is respectfully requested. Applicant respectfully requests early and favorable notification to that effect.

Respectfully submitted,

Dated: February 22, 2001

By: 

Joseph A. Mahoney
Registration No. 38,956
Mayer, Brown, Rowe & Maw
P.O. Box 2828
190 S. LaSalle Street
Chicago, IL 60690-2828
(312) 701-8979

Version with Markings to Show Changes Made to the Claims

1. Please replace the paragraph beginning on page 4, line 17 with the following rewritten paragraph:

33. (Amended) The method of claim 101, [32] wherein the subject is eugonadal.

35. (Amended twice) The method of claim 101, [32] wherein the pharmaceutical is at least one of sildenafil[,] citrate, pentoxifylline, yohimbine, apomorphine, alprostadil, papavaerine, phentolamine, and combinations, salts, and enantiomers thereof.

36. (Amended twice) The method of claim 101, [32] wherein the pharmaceutical is sildenafil citrate.

41. (Amended twice) The method of claim 101, [32] wherein the composition comprises about [0.1%] 1.0% [to about 10%] w/w of testosterone.

42. (Amended twice) The method of claim 101, [41] wherein the composition [enhancer] comprises about 0.5% w/w to about 1.0% w/w [of] isopropyl myristate.

45. (Amended twice) The method of claim 101, [32] wherein the subject is hypogogadal.

48. (Amended twice) The method of claim 101, [32] wherein the subject is a man, [having a right/left upper arm/shoulder and an abdomen having a right and left side,] and the [administering comprises administering] the composition in administered to an area of skin selected from the group consisting of arm, shoulder, abdomen, back, and thigh. [to the right/left upper arms/shoulders and to the right/left sides of the abdomen once per day on alternate days.]

49. (Amended twice) The method of claim 101, [32] wherein the composition is administered to the subject in an amount to deliver to the skin [pharmaceutically effective amount of a steroid comprises] about 25 [75] mg to about 100 mg of testosterone per day.

57. (Amended) The method of claim 101, [32] wherein the pharmaceuticals is apomorphine.

58. (Amended) The method of claim 101, [32] wherein the composition is administered to the subject in an amount from about 2.5 g/day to about 10.0 g/day.

59. (Amended) The method of claim 101, [32] wherein the composition administered to the subject achieves a maximum serum testosterone concentration at between about 16 hours and about 22 hours after administration of the composition.

62. (Amended) The method of claim 101, [32] wherein in the composition is administered at least once per day.

64. (Amended) The method of claim 62, [63] wherein the administration is to same site for approximately 7 days.

75. (New) The method of claim 101, [32] wherein the composition comprises about 0.25% [0.1%] to about 5% [10.0%] w/w testosterone.

76. (Amended) The method of claim 101, [75] wherein the composition comprises about 1% w/w testosterone.

77. (Amended) The method of claim 101, [75] wherein the composition comprises about 0.1% w/w testosterone.

78. (Amended) The method of claim 101, [32] wherein the gelling agent [composition] comprises [about 0.1% to about 5.0% w/w] polyacrylic acid.

79. (Amended) The method of claim 78, wherein the [composition comprises about 0.9% w/w] polyacrylic acid is in an amount of about 0.9% w/w of the composition.

80. (Amended) The method of claim 101, [32] wherein the composition comprises about 0.25% [0.1%] to about 2.5% [5.0%] w/w isopropyl myristate.

81. (Amended) The method of claim 101, [32] wherein the composition comprises about 0.5% w/w isopropyl myristate.

82. (Amended) The method of claim 101, [32] wherein the composition comprises about 40.0% [30.0%] to about [98%] 90% w/w ethanol.

83. (Amended) The method of claim 101, [83] wherein the composition comprises about 72.5% w/w ethanol.

88. (Amended) The method of claim 101, [32] wherein the pharmaceutical is a phosphodiesterase inhibitor.

89. (Amended) The method of claim 88, wherein the phosphodiesterase inhibitor comprises at least one of type III, type IV, type V, and mixtures thereof.

90. (Amended) The method of claim 89, wherein the phosphodiesterase inhibitor is type V.

91. (Amended) The method of claim 90, wherein the phosphodiesterase inhibitor is administered to the subject in about a 50 mg oral dose.

92. (Amended) The method of claim 90, wherein the phosphodiesterase inhibitor is administered about 20 minutes to about 60 minutes before sexual intercourse.

93. (Amended) The method of claim 88, wherein the phosphodiesterase inhibitor is administered in the form of at least one of a salt, ester, amide, prodrug, and mixtures thereof.

97. (Amended) The method of claim 101, [32] wherein the pharmaceutical is administered about 20 minutes to about 60 minutes before sexual intercourse.

98. (Amended) The method of claim 101, [32] wherein the composition and the pharmaceutical are components of a kit.

99. (Amended) The method of claim 98, wherein the kit further comprises a set of instructions.

Version with Markings to Show Changes Made to the Specification

-- Testosterone circulates in the blood 98% bound to protein. In men, approximately 40% of the binding is to the high-affinity sex hormone binding globulin ("SHBG"). The remaining 60% is bound weakly to albumin. Thus, a number of measurements for testosterone are available from clinical laboratories. The term "free" testosterone as used herein refers to the fraction of testosterone in the blood that is not bound to protein. The term "total testosterone" or "testosterone" as used herein means the free testosterone plus protein-bound testosterone. The term "bioavailable testosterone" as used herein refers to the non-SHBG bound testosterone and includes [that] testosterone weakly bound to albumin.—

2. Please replace the paragraph beginning on page 14, line 13, with the following rewritten paragraph:

-- Toxicity and therapeutic efficacy of the active ingredients can be determined by standard pharmaceutical procedures, *e.g.*, for determining LD_{50} (the dose lethal to 50% of the population) and the ED_{50} (the dose therapeutically effective in 50% of the population). The dose ratio between toxic and therapeutic effects is the therapeutic index and it can be expressed as the ratio LD_{50}/ED_{50}. Compounds which exhibit large therapeutic [induces] indices are preferred. While compounds that exhibit toxic side effects may be used, care should be taken to design a delivery system that targets such compounds to the site of affected tissue in order to minimize potential damage to uninfected cells and, thereby, reduce side effects.—

3. Please replace the paragraph beginning on page 41, line 11, with the following rewritten paragraph:

-- Patients receiving AndroGel® or the testosterone patch achieve "hormonal steady state" only after long-term treatment. Specifically, data involving FSH and LH show that these hormones do not achieve steady-state until many weeks after treatment. Because testosterone concentrations are negatively inhibited by FSH and [LG] LH, testosterone levels do not achieve true steady state until these other hormones also achieve steady state. However, because these hormones regulate only endogenous testosterone (which is small to begin with in hypogonadal men) in an intact feedback mechanism (which may not be present depending on the cause of hypogonadism), the level of FSH and/or LH may have little effect on the actual testosterone levels achieved. The net result is that the patients do not achieve a "hormonal steady state" for testosterone even though the C_{avg}, C_{min}, and C_{max} for testosterone remains [relative] relatively constant after a few days of treatment.--